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Author Affiliation:

¹Ophth Pharma (Pvt) Ltd Karachi, Pakistan

²Department of Chemistry University Of Karachi, Pakistan

³Sindh institute of urology and transplant Karachi, Pakistan

✉ Corresponding author:

Ophth Pharma (Pvt) Ltd Karachi, Pakistan

E-Mail; - abdulmunan17@gmail.com

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A novel method for preparation of Antibacterial and Atraumatical Surgical Sutures

Abdul Munan^{1,2✉}, Akhtar Jamal Khan^{1,3}, Mahwash Khan¹, Ghulam Abbas¹, Suleman Khan¹, Muhammad Ishaq Nazir¹, Fakhar-e-Alam¹, Abubakar Iqbal^{1,2}

ABSTRACT

To reduce some risk associated problems such as tissue trauma and surgical site infection a novel Atraumatical and anti-bacterial sutures were developed by silicon and triclosan mixed coating. For this purpose a Poly glycolic acid thread USP No1, Silk USP No1, and Chromic Catgut USP No 1 were selected. The different variables such as tensile strength, diametric variation, moisture content before and after coating, degradation in balanced salt solution, phosphate buffer of pH 7.4, and 93% isopropyl alcohol at 37c° for 28 days studies were thoroughly carried out of purposed sutures. The antibacterial activity of purposed sutures was also determined by calculating MIC Values. Similarly coating concentration of triclosan of prepared purposed sutures were estimated with compared to Local pharmacy available triclosan impregnated sutures.

Key Words: Atraumatical, Antimicrobial, SSI, Tensile Strength, Degradation

1. INTRODUCTION

Surgical suture is a medical device generally used for stitching wounds after surgery. It is composed of needle and thread. Needles and threads are different categories according to type of material, thread size and shape of needle. Thread is the main part of suture which must be smooth free from germs. The direct involvement of wound closing therefor very important to be sterile or antibacterial, if not, it may cause of surgical site infection (Obermeier et al. 2018; Haghighat et al. 2013).

The systematic extensive survey of literature has revealed that some experiments have been carried out to make sutures antibacterial and smooth, by coating with triclosan, Chlorohexidine, tetracycline and with Low density Silicon and wax respectively (Al-Haddad et al. 2015). The coating with triclosan, Chlorohexidine and tetracycline are used for making suture antibacterial while Low density silicon and waxes have used for making braided threads smooth (Franco et al. 2019). Surgical suture coating with antibacterial material and siliconization is necessary to avoid the wide ranging of deleterious effects of SSIs and their treatment particularly in the context of

increasing numbers of surgical procedures, there is a clinical need to reduce the incidences of SSIs. SSIs are multifunctional with patient factor like as age comorbidities including diabetes, and immunosuppression contributing to their development, along with surgical factors (Ahmed et al. 2019).

SSIs may raise when bacteria colonise the suture material creating a biofilm as it passes through the skin (Leaper et al. 2010). This biofilm establishes an immunity from both antibacterial treatment and host immune system. Once this biofilm develops there is an increase chance of SSI developing (Overhage et al. 2008).

Another severe problem also associated with the surgical sutures that are tissue trauma. This is cause of rupturing of tissue during stitching with sutures after surgery. This case become more severe with stitching of soft tissues by rough surface of sutures, but it has greater association with braided sutures than monofilament sutures. The rough surface of sutures can be smooth by coating of any suitable materials (Joseph et al. 2017; Matarasso et al. 2013; Tajirian & Goldberg, 2010).

Here is a new type of antibacterial and trauma free suture has been evaluated by mixed coating of triclosan and silicon which is free from SSI and Tissue trauma problem. The triclosan is a broad spectrum antibacterial material which is used in human products for from last three decades (Tajirian & Goldberg, 2010; Franco et al. 2019; Jones et al. 2019).

2. MATERIAL AND METHOD

All reagent were analytical grade and used directly without further purification. The Low density silicon from Germany GmB, Triclosan (99%), phosphate buffer pH 7.4 and n-Hexane were from J.K Enterprises. The microbial culture S. Aureus ATCC 6383 and trypto soya agar were from Mosa Jee Adam Karachi Pakistan. The same USP no 1 Suture threads, chromic catgut, silk, PGA and Polyester were purchased from Mete Bio made (Pvt) Ltd China.

Instrumentals

The spectrophotometer 1601 Shimadzu Japan, Micrometre from Mitutoyo Japan of having 0.02mm least count, Tensilemeter Mark - 10 USA, of measuring range 0.0 – 100 kgf, Moisture Analyser made of Seiko Japan and incubator of temperature range 35 – 37 made of Memmert Germany and Electronic Balance Shimadzu Japan were used for preparations and investigation.

General Procedure:-

Preparation of coating Solution:-

A 1.8 gram Triclosan and 5 ml Silicon Oil having density 0.96g/m³ were transferred into 250ml volumetric flask, dissolved in n-Hexane and made the volume with same solvent.

Coating Procedure:-

The respective threads were dipped in the coating solution for 10 to 30 sec and dried at 40°C for 10 mins, and repeated same procedure for two or three times until the perfect coating had done. The coating layer can be estimated by weighing.

Selection of Sutures Threads:-

The braided threads of sutures with USP number one in size were selected due to their roughness of surface and ability for colonization for bacteria. They are namely PGA (Poly glycolic Acid), Silk, Polyester and Chromic Catgut.

Coating Layer Estimation on surface of Suture:-

The coating of triclosan and silicon over the surface of sutures was estimated spectrophotometrically. The coated sutures were dissolved in n-Hexane in 25ml volumetric flask and sonicated, the volume was made up with same solvent. The absorbance was recorded against blank at 280nm (Obermeier et al. 2014).

Media preparation for Antibacterial Activity:-

The antibiotic agar media was accurately weighed 30.0gm and transferred into 1000ml media bottle and dissolved with purified water. The media was autoclaved at 121°C temperature for 15 mins (Bonev et al. 2008; Cooper, 1955).

Local pharmacy available antibacterial sutures:-

The Vicryl+ from Ethicon USA and Glytin+ from Huaiyin Medical Instruments Factory China, were purchased from local pharmacy, and their triclosan coating quantity was estimated with compared to purposed sutures.

3. RESULTS

Optimization Parameters:-

The different variable such as Tensile Strength, Degradation in phosphate buffer pH7.4, Degradation of PGA and Chromic Catgut in balanced salt solution (BSS), Diametric variation and tensile strength of chromic catgut at IPA 90% solution, Solvent Effect on coating, Coating effect on surface of suture, Moisture Content, Diameter or on Metric Size Effect, Study of Zone Of Inhibition at different concentration of coated material on surface of thread with compared to vicryl+ from Ethicon and Glytin+ from Huaiyin Medical Instrument Factory China, were studied for 28 days of selected sutures to optimize the coating effects in threads. The vicryl+ and Glytin+ sutures were also kept in incubation to study the degradation with compared to purposed sutures.

Tensile strength of selected sutures with respective of time

The tensile strength was measured as according to USP monograph/guidelines, after and before coating with coating mixture. It was observed that there is no change in tensile strength before and after coating in especially in non-observable selected suture, PGA, Silk, Polyester and chromic catgut. The observed results are tabulated in table-02. (Observation were made at ambient temperature).

Table 01:- Tensile strength of selected sutures with respective of time

Suture type	Tensile strength before coating	After coating	Time
PGA 1(Braided)	58.2	58.5	1 Day
	58.1	57.84	7 Days
	58.1	58.2	14 Days
	58.1	58.4	28 Days
Chromic Cat Gut 01	57.8	57.9	1 Day
	59.8	59.2	7 Days
	58.8	58.1	14 Days
	60.1	59.1	28 Days
Silk 01(Braided)	42.9	44.6	1 Day
	52.0	52.1	7 Days
	53.1	54.1	14 Days
	54.1	53.9	28 Days

Degradation study in Phosphate Buffer pH 7.4:-

The degradation study was done only in absorbable suture i.e. (PGA and Chromic catgut). The PGA suture were put into phosphoric buffer pH 7.4 before and after coating and incubated at 37°C for 28 days. At different interval of time (7 days, 14 days, 20 days and 28 days). The incubated sutures were studies with respective tensile strength. The observed results of PGA 1 and chromic catgut 1 sutures are tabulated in table-02.

Table-02:- Degradation with respective Tensile Strength in Phosphate Buffer pH 7.4

Suture Type	Tensile strength coated Suture	without coated	Time(Days)
PGA1 (Braided)	54.80N	58.85	1
	58.41	54.41	7
	54.25	54.80	14
	54.90	53.9	20
	54.23	52.45	28
Chromic Catgut 01	58.10	58.1	1
	54.90	54.1	7
	54.10	47.60	14

	50.30	40.31	28
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Degradation study in Balanced Salt Solution (BSS):-

The degradation of PGA and Chromic Catgut were studied by keeping threads in BSS solution for 28 days at 37c for incubation. The samples of were tested after 7,14 and 28 days of interval of time. The degradation of samples was measured by means of tensile strength. The observed results are tabulated in Table-03:-

Table 03;- Degradation by means of T.S in Balanced Salt Solution

Suture Type	Time(Days)	T.S & Dia Coated	T.S & Dia Uncoated	Glytin+	Vicryl +	USP Dia (mm)
PGA 1(Braided)	1					
	7	0.51mm,56N	0.51mm,56N	0.5mm,55.75N	0.51mm,54.85	
	14	0.5 mm,55.9	0.51mm,55.9	0.5mm,55.28	0.5mm,54.56	
	28	0.5 mm,55.7	0.50mm,55.12	0.5mm,55.2	0.5mm,55	0.4-0.499
		0.5 mm,54.9	0.5mm,54.8	0.5mm,54.9	0.5mm,53.9	
Chromic 1 Cat Gut	1	0.61mm,----	0.6mm, 54.5			
	7	0.61mm,50.6	0.60mm,54.8	----	----	0.5-0.599
	14	0.60mm,40.6	0.61mm,50.8			
	28	0.61mm,37.85	0.61mm,40.3			

Diametric variation and tensile strength of chromic catgut at IPA 93% solution:

The diametric variation of coated and uncoated chromic catgut sutures were done on 93% isopropyl alcohol having preservatives of sodium benzoate and ethanolamine. The sutures were kept in solution at 37°C for 28 days incubation. The tensile strength and variation in diameter were measured at 1 day, 7 days, 14 days, 20 days and 28 days interval of time, all selected chromic catgut sutures were previously irradiated with gamma radiations. The Obtained results are shown in Table 04.

Table-04;- Diametric variation and tensile strength of chromic catgut at IPA 93% solution

Tensile strength without coated sutures(newton)	Tensile strength uncoated sutures(Newton)	Diameter of coated sutures (mm)	Diameter of uncoated sutures(mm)	Time(Days)
54.91	54.6	0.73	0.73	1
54.85	50.8	0.75	0.74	7
50.80	47.60	0.77	0.75	14
50.30	39.10	0.77	0.76	20
50.11	39.05	0.77	0.76	28

Microbial Activity of proposed Sutures:-

An in-vitro Study of purposed sutures was conducted and their minimum zones of inhibitory were determined at different concentrations such as 1.0%, 1.5% and 1.8% of coated solutions. The coated and uncoated sutures were inserted in media plates which were incubated at 37c for 24 hours. After completion of incubation time, the zones were observed which are shown in Fig-1 and 2.

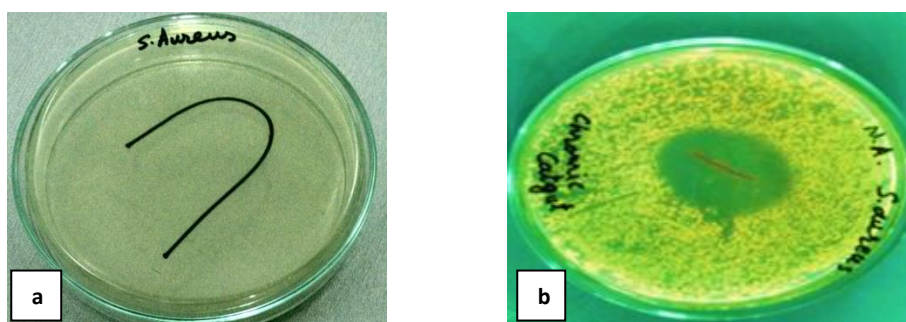


Fig 1: a) Bacterial activity of without Silicon coated sutures in staph aureus b) Bacterial activity of without Silicon coated sutures in staph aureus



Fig 2a: Bacterial activity of without Silicon coated sutures in B.subtillis



Fig 2b: Bacterial activity of Silicon coated sutures in B.subtillis

MIC Values of proposed sutures with compare to other triclosan impregnated sutures available in Local Pharmacy;-

The local pharmacy available sutures were also inserted in cultured media that the obtained MIC Values compared with values of purposed sutures. The obtained MIC Values of inhibitory are shown in Table 05;-

Table-05;- Minimum Inhibitory Concentrations of proposed and other sutures;

S.NO	Purposed Sutures	Mic Values	Available Antibacterial Sutures	Mic Values
1	PGA 1	20.1 mcg	Vicryl + from Ethicon	18.9 mcg
2	Chronic Catgut 1	22.2 mcg	Glytin+ from Hanyain	16.1 mcg
3	Silk 1	20.4 mcg		

MIC;- Minimum Inhibitory concentration;-

Moisture Content;-

Moisture content of all suture were tested before and after coating, while all sutures were kept under ambient conditions, the observed measurements of moisture content of all selected sutures are tabulated in Table;- 06.

Table-06;- Moisture Content

Moisture content Before Coating (%Avg)	Moisture content After Coating (%Avg)	% Difference	Type of Sutures	Time (Days)
0.61	0.61	0.00	PGA 1	1-28
1.17	0.59	0.58	Chromic Cat Gut1	1-28
1.28	1.28	0.00	Silk1	1-28
0.95	0.94	-0.01	Poly Ester 0	1-28

Solvent Effect on Coating:-

The Coating mixture was prepared in different solvents such as n-Hexane, Chloroform, Acetonitrile and isopropyl alcohol as according to general preparation procedure. All coating mixtures were applied on coating of all type of sutures (n=3). The diameter and weight of thread were measured before and after coating, to determine the solvent effect in coating on threads. The observed results are tabulated in table;-07.

Table 07;- Solvent Effect on Coating

Thread type	Coated Concentration of triclosan by means of Absorbance on sutures	Solvent
PGA 1	0.5468	n-Hexane
Chromic Catgut 1	0.5962	
Silk 1	0.5871	
Polyester 0	0.429	
PGA 1	0.298	Chloroform
Chromic Catgut 1	0.299	
Silk 1	0.301	
Polyester 0	0.311	
PGA 1	0.0718	Acetonitrile
Chromic Catgut 1	0.0668	
Silk 1	0.0720	

Solution Concentrations and Coating:-

Three different coating solutions of having concentrations 1.0%, 1.5% and 1.8% were prepared as according to the general procedure. The coating concentrations were tested on PGA1 after coating by using Spectrophotometer 1601 at wave length of 280 nm. The coating of proposed sutures was compared with locally purchase triclosan impregnated sutures. The observed absorbance and calculated results are tabulated in table 08;-

Table-08;-Solution Concentrations and Coating

Suture Type	%Concentration of Coating Solution	Absorbance	FDA Approved Limit	Coated Concentration on suture
	1.0%	0.2805		13.7 mcg

PGA 1	1.5%	0.5756	24mcg/cm of PGA thread size 1	28.1 mcg
	1.8%	0.8046		39.26 mcg
Vicryl+		0.2325		11.3 mcg
Glytin+		0.0787		3.8 mcg

4. DISCUSSION

The study of variables indicates that there is no any reasonable change found by coating with triclosan and silicon mixture. The comparative degradation of purposed (PGA 1) and local pharmacy available sutures (Vicryl+ from Ethicon, and Glytine+ from Hanyain Medical) in BSS, Phosphate Buffer pH 7.4 and 90% isopropyl Alcohol Solution is nearly same, which proves that the purposed sutures are compatible for usage in surgeries.

n-Hexane is more suitable solvent for coating due to its volatile nature and dissolving ability of coating mixture. The moisture content of thread (PGA 1) at 65% humidity and 30°C temperature throughout 28 days show that absorption of moisture on PGA thread remains same while uncoated thread gains moisture gradually. The Mic Values of purposed sutures and other locally available sutures (Vicryl+ and Glytine) are also support the perfectness of purposed sutures.

5. CONCLUSION

The in-vitro studies of purposed antibacterial sutures are considerably Atraumatic and free from surgical site infections due to its smoothness of surface and antibacterial activity. The degradation of PGA with compare to vicryl+ and Glytine+ demonstrates that the purpose sutures are compatible for surgery.

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Ethical approval

Not applicable.

Conflict of Interest:

The authors declare that there are no conflicts of interests.

Data and materials availability:

All data associated with this study are present in the paper.

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